LG-4878 REV. 9/89

8EHQ-1192-13158

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Environmental Protection Agency
401 M Street., S.W.
Washington, D.C. 20460
Attn: Section 8(e) Coordinator (CAP Agreement)

8EHQ-92-13158
INIT
8892001961

Dear Coordinator:

8ECAP-0025

On behalf of the Regulatee and pursuant to Unit II B.1.b. and Unit II C of the 6/28/91CAP Agreement, E.I. Du Pont de Nemours and Co. hereby submits (*in triplicate*) the attached studies. Submission of this information is voluntary and is occasioned by unilateral changes in EPA's standard as to what EPA now considers as reportable information. Regulatee's submission of information is made solely in response to the new EPA §8(e) reporting standards and is not an admission: (1) of TSCA violation or liability; (2) that Regulatee's activities with the study compounds reasonably support a conclusion of substantial health or environmental risk or (3) that the studies themselves reasonably support a conclusion of substantial health or environmental risk.

The "Reporting Guide" creates new TSCA 8(e) reporting criteria which were not previously announced by EPA in its 1978 Statement of Interpretation and Enforcement Policy, 43 Fed Reg 11110 (March 16, 1978). The "Reporting Guide states criteria which expands upon and conflicts with the 1978 Statement of Interpretation. Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" raises significant due processes issues and clouds the appropriate reporting standard by which regulated persons can assure TSCA Section 8(e) compliance.

For Regulatee,

8ECAP

Mark H. Christman
Counsel
Legal D-7158
1007 Market Street
Wilmington, DE 19898
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RECEIVED 9/18/95

ATTACHMENT 1

Submission of information is made under the 6/28/91 CAP Agreement, Unit II. This submission is made voluntarily and is occasioned by recent changes in EPA's TSCA §8(e) reporting standard; such changes made, for the first time in 1991 and 1992 without prior notice and in violation of Regulatee's constitutional due process rights. Regulatee's submission of information under this changed standard is not a waiver of its due process rights; an admission of TSCA violation or liability, or an admission that Regulatee's activities with the study compounds reasonably support a conclusion of substantial risk to health or to the environment. Regulatee has historically relied in good faith upon the 1978 Statement of Interpretation and Enforcement Policy criteria for determining whether study information is reportable under TSCA §8(e), 43 Fed Reg 11110 (March 16, 1978). EPA has not, to date, amended this Statement of Interpretation.

After CAP registration, EPA provided the Regulatee the June 1, 1991 "TSCA Section 8(e) Reporting Guide". This "Guide" has been further amended by EPA, EPA letter, April 10, 1992. EPA has not indicated that the "Reporting Guide" or the April 1992 amendment supersedes the 1978 Statement of Interpretation. The "Reporting Guide" and April 1992 amendment substantively lowers the Statement of Interpretation 's TSCA §8(e) reporting standard[2]. This is particularly troublesome as the "Reporting Guide" states criteria, applied retroactively, which expands upon and conflicts with the Statement of Interpretation.[3] Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" and the April 1992 amendment clouds the appropriate standard by which regulated persons must assess information for purposes of TSCA §8(e).

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[2]In sharp contrast to the Agency's 1977 and 1978 actions to soliciting public comment on the proposed and final §8(e) Policy, EPA has unilaterally pronounced §8(e) substantive reporting criteria in the 1991 Section 8(e) Guide without public notice and comment, See 42 Fed Reg 45362 (9/9/77), "Notification of Substantial Risk under Section 8(e): Proposed Guidance".

[3]A comparison of the 1978 Statement of Interpretation and the 1992 "Reporting Guide" is a appended.

Throughout the CAP, EPA has mischaracterized the 1991 guidance as reflecting "longstanding" EPA policy concerning the standards by which toxicity information should be reviewed for purposes of §8(e) compliance. Regulatee recognizes that experience with the 1978 Statement of Interpretation may cause a review of its criteri. Regulatee supports and has no objection to the Agency's amending reporting criteria *provided that* such amendment is not applied to the regulated community in an unfair way. However, with the unilateral announcement of the CAP under the auspices of an OCM enforcement proceeding, EPA has wrought a terrific unfairness since much of the criteria EPA has espoused in the June 1991 Reporting Guide and in the Agency's April 2, 1992 amendment is new criteria which does not.exist in the 1978 Statement of Interpretation and Enforcement Policy.

The following examples of new criteria contained in the "Reporting Guide" that is not contained in the Statement of Interpretation follow:

o even though EPA expressly disclaims each "status report" as being preliminary evaluations that should not be regarded as final EPA policy or intent[4], the "Reporting Guide" gives the "status reports" great weight as "sound and adequate basis" from which to determine mandatory reporting obligations. ("Guide" at page 20).

o the "Reporting Guide" contains a matrix that establishes new numerical reporting "cutoff" concentrations for acute lethality information ("Guide" at p. 31). Neither this matrix nor the cutoff values therein are contained in the Statement of Interpretation. The regulated community was not made aware of these cutoff values prior to issuance of the "Reporting Guide" in June, 1991.

othe "Reporting Guide" states new specific definitional criteria with which the Agency, for the first time, defines as 'distinguishable neurotoxicological effects'; such criteria/guidance not expressed in the 1978 Statement of Interpretation.[5];

othe "Reporting Guide" provides new review/ reporting criteria for irritation and sensitization studies; such criteria not previously found in the 1978 Statement of Interpretation/Enforcement Policy.

othe "Reporting Guide" publicizes certain EPA Q/A criteria issued to the Monsanto Co. in 1989 which are not in the Statement of Interpretation; have never been published in the Federal Register or distributed by the EPA to the Regulatee. Such Q/A establishes new reporting criteria not previously found in the 1978 Statement of Interpretation/Enforcement Policy .

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[4]The 'status reports' address the significance, if any, of particular information reported to the Agency, rather than stating EPA's interpretation of §8(e) reporting criteria. In the infrequent instances in which the status reports contain discussion of reportability, the analysis is invariably quite limited, without substantial supporting scientific or legal rationale.

[5] *See, e.g,* 10/2/91 letter from Du Pont to EPA regarding the definition of 'serious and prolonged effects' as this term may relate to transient anesthetic effects observed at lethal levels; 10/1/91 letter from the American Petroleum Institute to EPA regarding clarification of the Reporting Guide criteria.

In discharging its responsibilities, an administrative agency must give the regulated community fair and adequate warning to as what constitutes noncompliance for which penalties may be assessed.

> Among the myriad applications of the due process clause is the fundamental principle that statutes and regulations which purport to govern conduct must give an adequate warning of what they command or forbid.... Even a regulation which governs purely economic or commercial activities, if its violation can engender penalties, must be so framed as to provide a constitutionally adequate warning to those whose activities are governed.

Diebold, Inc. v. Marshall, 585 F.2d 1327, 1335-36 (D.C. Cir. 1978). *See also*, Rollins Environemntal Services (NJ) Inc. v. U.S. Environmental Protection Agency, 937 F. 2d 649 (D.C. Cir. 1991).

While neither the are rules, This principle has been applied to hold that agency 'clarification', such as the Statement of Interpretation, the "Reporting Guide" nor the April 1992 amendments will not applied retroactively.

> ...a federal court will not retroactively apply an unforeseeable interpretation of an administrative regulation to the detriment of a regulated party on the theory that the post hoc interpretation asserted by the Agency is generally consistent with the policies underlying the Agency's regulatory program, when the semantic meaning of the regulations, as previously drafted and construed by the appropriate agency, does not support the interpretation which that agency urges upon the court.

Standard Oil Co. v. Federal Energy Administration, 453 F. Supp. 203, 240 (N.D. Ohio 1978), aff'd sub nom. Standard Oil Co. v. Department of Energy, 596 F.2d 1029 (Em. App. 1978):

The 1978 Statement of Interpretation does not provide adequate notice of, and indeed conflicts with, the Agency's current position at §8(e) requires reporting of all 'positive' toxicological findings without regard to an assessment of their relevance to human health. In accordance with the statute, EPA's 1978 Statement of Interpretation requires the regulated community to use scientific judgment to evaluate the significance of toxicological findings and to determining whether they reasonably support a conclusion of a substantial risk. Part V of the Statement of Interpretation urges persons to consider "the fact or probability" of an effect's occurrence. Similarly, the 1978 Statement of Interpretation stresses that an animal study is reportable only when "it contains reliable evidence ascribing the effect to the chemical." 43 Fed Reg. at 11112. Moreover, EPA's Statement of Interpretation defines the substantiality of risk as a function of both the seriousness of the effect and the probability of its occurrence. 43 Fed Reg 11110 (1978). Earlier Agency interpretation also emphasized the "substantial" nature of a §8(e) determination. See 42 Fed Reg 45362, 45363

(1977). [Section 8(e) findings require "extraordinary exposure to a chemical substance...which critically imperil human health or the environment"].

The recently issued "Reporting Guide" and April 1992 Amendment guidance requires reporting beyond and inconsistent with that required by the Statement of Interpretation. Given the statute and the Statement of Interpretation's explicit focus on substantial human or environmental risk, whether a substance poses a "substantial risk" of injury requires the application of scientific judgment to the available data on a case-by-case basis.

If an overall weight-of-evidence analysis indicates that this classification is unwarranted, reporting should be unnecessary under §8(e) because the available data will not "reasonably support the conclusion" that the chemical presents a substantial risk of serious adverse consequences to human health.

Neither the legislative history of §8(e) nor the plain meaning of the statute support EPA's recent lowering of the reporting threshold that TSCA §8(e) was intended to be a sweeping information gathering mechanism. In introducing the new version of the toxic substances legislation, Representative Eckhart included for the record discussion of the specific changes from the version of H. R. 10318 reported by the Consumer Protection and Finance Subcommittee in December 1975. One of these changes was to modify the standard for reporting under §8(e). The standard in the House version was changed from "causes or contributes to an unreasonable risk" to "causes or significantly contributes to a substantial risk". This particular change was one of several made in TSCA §8 to avoid placing an undue burden on the regulated community. The final changes to focus the scope of Section 8(e) were made in the version reported by the Conference Committee.

The word "substantial" means "considerable in importance, value, degree, amount or extent". Therefore, as generally understood, a "substantial risk" is one which will affect a considerable number of people or portion of the environment, will cause serious injury and is based on reasonably sound scientific analysis or data. Support for the interpretation can be found in a similar provision in the Consumer Product Safety Act. Section 15 of the CPSA defines a "substantial product hazard" to be:

> "a product defect which because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise, creates a substantial risk of injury to the public."

Similarly, EPA has interpreted the word 'substantial' as a quantitative measurement. Thus, a 'substantial risk' is a risk that can be quantified, *See,* 56 Fed Reg 32292, 32297 (7/15/91). Finally, since information pertinent to the exposure of humans or the environment to chemical substances or mixtures may be obtained by EPA through Sections 8(a) and 8(d) regardless of the degree of potential risk, §8(e) has specialized function. Consequently, information subject to §8(e) reporting should be of a type which would lead a reasonable man to conclude that some type action was required immediately to prevent injury to health or the environment.

Attachment

Comparison:

Reporting triggers found in the 1978 "Statement of Interpretation/ Enforcement Policy",43 Fed Reg 11110 (3/16/78) and the June 1991 *Section 8(e) Guide.*

TEST TYPE	1978 POLICY CRITERIA EXIST?	New 1991 GUIDE CRITERIA EXIST?
ACUTE LETHALITY		
Oral	N}	Y}
Dermal	N}	Y}
Inhalation (Vapors)	}[6]	}[7]
aerosol	N}	Y}
dusts/ particles	N}	Y}
SKIN IRRITATION	N	Y[8]
SKIN SENSITIZATION (ANIMALS)	N	Y[9]
EYE IRRITATION	N	Y[10]
SUBCHRONIC (ORAL/DERMAL/INHALATION)	N	Y[11]
REPRODUCTION STUDY	N	Y[12]
DEVELOPMENTAL TOX	Y[13]	Y[14]

[6] 43 Fed Reg at 11114, comment 14:
"This policy statements directs the reporitng of specifiec effects when unknown to the Administrator. Many routine tests are based on a knowledge of toxicity associated with a chemicalL unknown effects occurring during such a range test may have to be reported if they are those of concern tot he Agency and if the information meets the criteria set forth in Parts V and VII."

[7] Guide at pp.22, 29-31.

[8] Guide at pp-34-36.

[9] Guide at pp-34-36.

[10] Guide at pp-34-36.

[11] Guide at pp-22; 36-37.

[12] Guide at pp-22

[13] 43 Fed Reg at 11112
"Birth Defects" listed.

[14] Guide at pp-22

NEUROTOXICITY	N	Y[15]
CARCINOGENICITY	Y[16]	Y[17]
MUTAGENICITY		
In Vitro	Y}[18]	Y} [19]
In Vivo	Y}	Y}
ENVIRONMENTAL		
Bioaccumulation	Y}	N
Bioconcentration	Y}[20]	N
Oct/water Part. Coeff.	Y}	N
Acute Fish	N	N
Acute Daphnia	N	N
Subchronic Fish	N	N
Subchronic Daphnia	N	N
Chronic Fish	N	N
AVIAN		
Acute	N	N
Reproductive	N	N
Reprodcutive	N	N

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[15]Guide at pp-23; 33-34.

[16]43 Fed Reg at 11112
"Cancer" listed

[17]Guide at pp-21.

[18]43 Fed Reg at 11112; 11115 at Comment 15
"Mutagenicity" listed/ *in vivo* vs *invitro* discussed; discussion of "Ames test".

[19]Guide at pp-23.

[20]43 Fed Reg at 11112; 11115 at Comment 16.

(9)

CAS: 90-12-0; 108-82-7
Chem: Alpha-methyl naphthalene; diisobutyl carbinol
Title: Preliminary Toxicity Investigation
Date: 1/11/51
Summary of effects: Alpha-methyl naphthalene-incoordination and muscle weakness; DIBC- incoordination

Medical Research Project No. MR-183

Preliminary Toxicity Investigation of 2-Tertiarybutyl Anthraquinone alpha-Methyl Naphthalene Diisobutyl Carbinol Organic Working Solution

The tests described below were carried out to get a rough idea of the toxicity characteristics of 2-tertiarybutyl anthraquinone and of the two solvents, alpha-methyl naphthalene and diisobutyl carbinol, in which it is ordinarily dissolved. An "Organic Working Solution" containing approximately 14% solids, 58% alpha-methyl naphthalene and 28% diisobutyl carbinol was also tested. The solids content of 14% was made up of 3.0% 2-tertiarybutyl anthraquinone, 8.1% 2-tertiarybutyl tetrahydro anthraquinone, and 3.9% by-product and impurities from 2-tertiarybutyl anthraquinone. The Organic Working Solution was included because it represents the solution with which workers came in contact in the process involving 2-tertiarybutyl anthraquinone.

I. 2-Tertiarybutyl Anthraquinone *

A. Acute Oral Toxicity (rats)

Approximate Lethal Dose >7500 mg/kg

B. Subacute Oral Toxicity (rat)

1. Each of 6 rats received 4000 mg/kg/day. Three died after 2 treatments, 2 died after 6 treatments, and 1 survived 10 treatments.
2. Each of six rats received 1500 mg/kg/day. All survived 10 treatments over a two-week period.

C. Skin Absorption Toxicity (rabbit)

Approximate Lethal Dose >7500 mg/kg

D. Clinical Observations

1. Acute oral tests - Rats receiving doses of 1000 mg/kg or more showed discomfort after treatment, and weight loss for several days following treatment.
2. Subacute oral tests - Rats receiving 4000 mg/kg/day showed marked weight loss with fatal termination in 5 of 6 rats. Rats receiving 1500 mg/kg/day showed weight loss during the treatment period but regained weight after treatment was stopped.
3. Skin absorption tests - No systemic reaction was noted.

E. Pathology

Rats dying from repeated doses of 4000 mg/kg showed ulceration of the stomach, and damage to the liver and kidney.

Rats receiving 1500 mg/kg/day and sacrificed 14 days after the 10th treatment showed evidence of mild kidney damage.

* Jackson Laboratory Sample - Approximately 90% 2-tertiarybutyl anthrquinone.

F. Skin irritation and Sensitization (guinea pig)
A paste consisting of 2 parts 2-tertiarybutyl anthraquinone and 1 part 95% ethanol failed to produce irritation when applied to the intact shaved skin of 10 guinea pigs. Further tests indicated that 2-tertiarybutyl anthraquinone did not produce allergic skin sensitization in the guinea pigs.

II Alpha-Methyl Naphthalene *

A. Acute Oral Toxicity (rat)
Approximate Lethal Dose = 7500 mg/kg

B. Subacute oral Toxicity (rat)
Each of six rats received 1500 mg/kg/day. All survived 10 treatments over a two-week period.

C. Skin Absorption Toxicity (rabbit)
Approximate Lethal Dose = 7500 mg/kg

D. Clinical Observations.
1. Acute oral tests - Rats receiving doses of 3375 mg/kg or more showed marked incoordination and muscular weakness lasting 24 - 48 hours. The rat receiving 7500 mg/kg died within 17 hours after treatment.
2. Subacute oral tests - Rats lost weight, looked ill, and developed bad tempers during treatment. Regained weight and were in good condition 14 days after 10th treatment.
3. Skin absorption tests - Local inflammation of skin occurred at the site of application. The rabbit receiving 7500 mg/kg refused food and was almost completely inactive until death 48 hours after treatment. Rabbit receiving 3750 mg/kg was inactive and refused food for 24 hours after treatment.

E. Pathology
1. Acute oral tests - Rat dying of 7500 mg/kg dose showed congestion of internal organs, and some evidence of kidney damage.
2. Subacute oral tests - No gross or micropathology was found in rats sacrificed 14 days after the 10th treatment.
3. Skin absorption tests - No organ pathology was detected except possible kidney damage.

F. Skin Irritation and Sensitization (guinea pig)
A 50% solution of alpha-methyl naphthalene in 95% ethanol was definitely irritating to intact shaved skin of 10 guinea pigs, but a 10% solution in ethanol was not irritating. Further tests indicated that alpha-methyl naphthalene did not

* Commercial grade, Velsicol Corporation

produce allergic skin sensitization in the guinea pigs.

III. Diisobutyl Carbinol *

A. Acute Oral Toxicity (rat)
Approximate Lethal Dose = 7500 mg/kg

B. Subacute Oral Toxicity (rats)
Each of six rats received 1500 mg/kg/day. All survived 10 treatments over a two-week period.

C. Skin Absorption Toxicity (rabbit)
Approximate Lethal Dose >10,000 mg/kg.

D. Clinical Observations
1. Acute oral tests - Incoordination and weakness similar to that observed with alpha-methyl naphthalene.
2. Subacute oral tests - Two of 6 rats lost weight during treatment; 4 of 6 gained. All showed slight incoordination during the treatment period.
3. Skin absorption tests - No signs of systemic toxicity were observed. Temporary local inflammation occurred at the site of application.

E. Pathology
1. Acute oral tests - Rat dying of 7500 mg/kg dose showed microscopic damage to the liver and kidney.
2. Subacute oral tests - No gross or microscopic pathology was detected in animals sacrificed 9 days after the 10th treatment.
3. Skin absorption tests - No organ pathology was detected.

F. Skin Irritation and Sensitization (guinea pig)
A 50% solution of diisobutyl carbinol in 95% ethanol produced mild inflammation of the intact skin of 3 of 10 guinea pigs. A 10% solution in 95% alcohol was non-irritant. Further tests indicated that diisobutyl carbinol did not produce allergic skin sensitization in the guinea pigs.

IV. Organic Working Solution

A. Approximate Lethal Dose (oral - rats) - [illegible] mg/kg.

B. Subacute Oral Toxicity (rats)
Each of six rats received 1000 mg/kg/day. All survived 10 treatments over a two-week period.

C. Skin Absorption Toxicity (rabbit)
Approximate Lethal Dose = 20,000 mg/kg.

* Commercial grade. Carbide & Carbon Chemicals Corporation

D. Clinical Observations

1. Acute oral tests - Rats receiving lethal doses showed marked incoordination and muscular weakness. Death occurred approximately 48 hours after treatment.
2. Subacute oral tests - Three of 6 rats gained a small amount of weight during treatment and 3 of 6 lost a small amount of weight. All gained satisfactorily after treatment was stopped.
3. Skin absorption tests - Rabbit receiving 20,000 mg/kg showed complete loss of appetite and extreme weakness. Went into shock and died 30 hours after treatment. Rabbit receiving 10,000 mg/kg showed almost complete loss of appetite for 8 - 10 days, and was inactive for several days after treatment.

E. Pathology

1. Acute oral tests - Congestion of internal organs, liver and kidney damage were observed.
2. Subacute oral tests - No gross or micropathology was detected in rats sacrificed 10 days after the 10th treatment.
3. Skin absorption tests - Rabbit which died showed mild damage to stomach, liver, adrenal glands, and kidney.

V. Summary and Discussion

The results of the above tests are summarized in Table I.

It can be seen from these experiments that 2-tertiary-butyl anthraquinone has the lowest acute oral toxicity for the rat, but also that none of the materials tested can be considered very toxic. The Organic Working Solution showed a higher acute toxicity than any of its components.

None of the materials tested showed a marked cumulative toxicity as judged by giving 10 doses, each 1/5 or less of the Approximate Lethal Dose, over a two-week period. Some cumulative toxicity, however, was evidenced by consistent weight loss during treatment with 2-tertiarybutyl anthraquinone and alpha-methyl naphthalene.

Diisobutyl carbinol and Organic Working Solution showed evidence of somewhat less cumulative toxicity in that weight remained essentially at a standstill during treatment.

Skin absorption toxicity was low for all four materials, but greatest for alpha-methyl naphthalene. The only materials which showed no systemic effect from skin application were 2-tertiarybutyl anthraquinone (in doses not exceeding 7500 mg/kg) and diisobutyl carbinol (in doses not exceeding 10,000 mg/kg).

TABLE 1

	Acute Toxicity (LD50)		Subacute Oral Toxicity No. Doses		Skin		Skin Absorption (LD50)
	mg/kg	Effects	mg/kg	Effects	Irritancy	Sensitization	mg/kg
Diisopropyl methylphosphonate	7750	Weight loss	10 x 1500	Temporary Discomfort	None	None	>7900
			10 x 4000	Death Liver and Kidney Damage			
Dimethyl methylphosphonate	7900	Incoordination Paralysis	10 x 1500	Discomfort Irritable	Erythema at 50% conc. (alc.) None at 10% conc. (alc.)	None	7900 mg/kg insufficient. Death in 48 hours.
Dibutyl phenyl phosphonate	7500	Incoordination Paralysis	10 x 1500	Temporary Discomfort	Mild erythema in 3/10 animals at 50% conc. (alc.) none at 10% conc. (alc.)	None	>10,000
Tri n-octyl phosphine oxide	5000	Incoordination Paralysis	10 x 1000	Temporary Discomfort	Not Tested	Not Tested	>10,000 mg/kg Chronic Skin Irritation. Probable liver and kidney damage. Death in 2 hours.

Irritation and sensitization tests on guinea pigs showed that alpha-methyl naphthalene and diisobutyl carbinol are somewhat irritating at 50% concentration but not at 10% concentration in 95% ethanol, while 2-tertiarybutyl anthraquinone was non-irritating. None of these materials produced allergic skin sensitization. The Organic Working Solution was not tested for skin irritation or sensitization on guinea pigs, but from its composition and its effect on rabbit skin one is justified in concluding that it would be similar in irritancy to alpha-methyl naphthalene and diisobutyl carbinol.

The over-all results of these preliminary tests suggest that the hazard of acute poisoning from contact with 2-tertiarybutyl anthraquinone, alpha-methyl naphthalene, diisobutyl carbinol, and Organic Working Solution should be low. Skin irritation may result from contact with the last three of these, but allergic skin sensitization appears to be improbable.

Subacute oral tests indicate that all of the four materials have some tendency to produce chronic toxic effects. This phase of the problem deserves further investigation if interest in the 2-tertiarybutyl anthraquinone process continues.

HASKELL LABORATORY OF
INDUSTRIAL TOXICOLOGY

John H. Foulger, M. D.
Director

BY: John A. Zapp, Jr., Ph. D.
Assistant Director

1-11-51
JAZ/emb
#20

Triage of 8(e) Submissions

Date sent to triage: _____ NON-CAP (CAP)

Submission number: 13158A TSCA Inventory: (Y) N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

(ATOX) (SBTOX) SEN (w/NEUR)

Group 3 - Elizabeth Margosches (1 copy each)

STOX	CTOX	EPI	RTOX	GTOX
STOX/ONCO	CTOX/ONCO	IMMUNO	CYTO	NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

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Notes:

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CECATS DATA:
Submission # RFHQ: 1192-13158 SEQ: A

TYPE: INT. SUPP FLWP

SUBMITTER NAME: E. I. Dupont de Nemours and Company

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
0570 REFER TO CHEMICAL SCREENING
0575 CAP NOTICE

VOLUNTARY ACTIONS:
0001 NO ACTION REPORTED
0002 STUDIES PLANNED/INITIATED
0003 NOTIFICATION OF WORKER/PUBLIC
0004 LABEL/MSDS CHANGES
0005 PROCESS/HANDLING CHANGES
0006 APP/USE DISCONTINUED
0007 PRODUCTION DISCONTINUED
0008 CONFIDENTIAL

SUB. DATE: 10/18/92 OTS DATE: 11/02/92 CSRAD DATE: 05/18/95

CHEMICAL NAME:

CAS#
90-12-0
108-82-7
unknown

Anthraquinone, 2-tertiarybutyl

INFORMATION TYPE:		P F C	INFORMATION TYPE:		P F C	INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04	0216	EPI/CLIN	01 02 04	0241	IMMUNO (ANIMAL)	01 02 04
0202	ONCO (ANIMAL)	01 02 04	0217	HUMAN EXPOS (PROD CONTAM)	01 02 04	0242	IMMUNO (HUMAN)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04	0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243	CHEM/PHYS PROP	01 02 04
0204	MUTA (IN VITRO)	01 02 04	0219	HUMAN EXPOS (MONITORING)	01 02 04	0244	CLASTO (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04	0220	ECOTOXICITY	01 02 04	0245	CLASTO (ANIMAL)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04	0221	ENV. OCCCIREL/FATE	01 02 04	0246	CLASTO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04	0222	EMER INCI OF ENV CONTAM	01 02 04	0247	DNA DAM/REPAIR	01 02 04
0208	NEURO (HUMAN)	01 02 04	0223	RESPONSE REQUST DELAY	01 02 04	0248	PRODUSE/PROC	01 02 04
(0209)	NEURO (ANIMAL)	01 02 04	0224	PROD/COMP/CHEM ID	01 02 04	0251	MSDS	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04	0225	REPORTING RATIONALE	01 02 04	0299	OTHER	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04	0226	CONFIDENTIAL	01 02 04			
(0212)	ACUTE TOX. (ANIMAL)	01 02 04	0227	ALLERG (HUMAN)	01 02 04			
(0213)	SUB ACUTE TOX (ANIMAL)	01 02 04	(0228)	ALLERG (ANIMAL)	01 02 04			
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04	0239	METAB/PHARMACO (ANIMAL)	01 02 04			
0215	CHRONIC TOX (ANIMAL)	01 02 04	0240	METAB/PHARMACO (HUMAN)	01 02 04			

TRIAGE RATIONALE	NON-CBI INVENTORY	ONCORSO REVIEW	SPECIES	TOXICOLOGICAL CONCERN:	USE:	PRODUCTION:
	(YES)	YES (DROP/REFER)	RAT	(LOW)		
CAS SR	NO	NO (CONTINUE)	RBT	MED		
	[illegible]	REFER	GP	HIGH		

[illegible]

13158A

L

2-Tertiarybutyl anthraquinone: Acute oral toxicity in rats is of low concern. Single oral doses to rats at levels up to 7,500 mg/kg were not lethal. At ≥1,000 mg/kg, rats exhibited discomfort and weight loss for several days following treatment.

L

2-Tertiarybutyl anthraquinone: Subacute oral toxicity in rats is of low concern based on two studies. In the first study, six rats received 4,000 mg/kg/day for ten days. All animals exhibited marked weight loss; 5/6 animals died. Necropsy revealed stomach ulceration and damage to the liver and kidney in animals that died. In the second study, six rats received 1,500 mg/kg/day for ten days; all animals survived. Weight loss occurred during treatment, but animals regained weight during the recovery period. Necropsy revealed mild kidney damage.

L

2-Tertiarybutyl anthraquinone: Acute dermal toxicity in rabbits is of low concern. Single dermal doses to rabbits at levels up to 7,500 mg/kg were not lethal. There were no clinical signs of toxicity.

L

2-Tertiarybutyl anthraquinone: Dermal irritation and sensitization in guinea pigs are of low concern. Application of the substance to the intact skin of ten guinea pigs did not cause irritation. The substance did not elicit an allergic skin reaction in guinea pigs.

L

Alpha-methyl naphthalene: Acute oral toxicity in rats is of low concern. Single oral doses to rats (1/dose) were lethal at 7,500 mg/kg. At ≥3,375 mg/kg, rats exhibited incoordination and muscular weakness. Necropsy revealed congestion of internal organs and kidney damage in the 7,500-mg/kg rat.

L

Alpha-methyl naphthalene: Subacute oral toxicity in rats is of low concern. Six rats received 1,500 mg/kg/day for ten days; all animals survived. Rats exhibited weight loss, ill appearance, and bad tempers during treatment, but regained weight during the recovery period. There were no pathological effects.

L

Alpha-methyl naphthalene: Acute dermal toxicity in rabbits is of low concern. Single dermal doses to rabbits (1/dose) were lethal at 7,500 mg/kg. At 3,375 and 7,500 mg/kg, rabbits were inactive and refused food. Local inflammation of the skin occurred at the application site. Necropsy revealed possible kidney damage.

M

Alpha-methyl naphthalene: Dermal irritation in guinea pigs is of moderate concern. Application of a 50% solution of the substance to the intact skin of ten guinea pigs resulted in irritation. A 10% solution was not irritating.

L

Alpha-methyl naphthalene: Dermal sensitization in guinea pigs is of low concern. The substance did not elicit an allergic skin reaction in guinea pigs.

L

Diisobutyl carbinol: Acute oral toxicity in rats is of low concern. Single oral doses to rats (1/dose) were lethal at 7,500 mg/kg. The 7,500-mg/kg rat exhibited incoordination and muscular weakness. Necropsy revealed microscopic damage to the liver and kidney in the 7,500-mg/kg rat.

L

Diisobutyl carbinol: Subacute oral toxicity in rats is of low concern. Six rats received 1,500 mg/kg/day for ten days; all animals survived. Weight loss occurred in two rats during treatment, and all exhibited slight incoordination. There were no pathological effects.

L

Diisobutyl carbinol: Acute dermal toxicity in rabbits is of low concern. Single dermal doses to rabbits at levels up to 10,000 mg/kg were not lethal. Temporary local inflammation occurred at the site of application. There were no other clinical signs or pathological effects.

L

Diisobutyl carbinol: Dermal irritation and sensitization in guinea pigs are of low concern. Application of a 50% solution of the substance to the intact skin of ten guinea pigs resulted in mild irritation in 3/10; a 10% solution did not cause irritation. The substance did not elicit an allergic skin reaction in guinea pigs.

L

Organic Working Solution: Acute oral toxicity in rats is of low concern. Single oral doses to rats (1/dose) were lethal at 5,000 mg/kg. At ≥5,000-mg/kg, rats exhibited incoordination and muscular weakness. Necropsy revealed congestion of internal organs and liver and kidney damage.

L

Organic Working Solution: Subacute oral toxicity in rats is of low concern. Six rats received 1,000 mg/kg/day for ten days; all animals survived. There were no significant clinical signs or pathological effects.

L

Organic Working Solution: Acute dermal toxicity in rabbits is of low concern. Single dermal doses to rabbits were lethal at 20,000 mg/kg. The 20,000-mg/kg rabbit exhibited loss of appetite and weakness. Loss of appetite and inactivity were seen in the 10,000-mg/kg rabbit. Necropsy revealed mild stomach, liver, adrenal, and kidney damage.